

I. THE TERMS OF THE PROTECTIVE ORDER

The treatment of confidential information in this litigation is governed by the terms of the December 13, 2002 Protective Order (the “PO”) entered by the Court and attached as Exhibit A.

Pursuant to the PO any party can designate documents as either “confidential” or “highly confidential”. To make such designations the producing party must believe in good faith that the designated material contains either:

Confidential Information: shall be limited to information that any producing party, including any third party, in good faith, believes to contain (a) proprietary or commercially sensitive information; (b) personal financial information; or (c) information that should otherwise be subject to confidential treatment under Rule 26(c)(7) of the Federal Rules of Civil Procedure.

Highly Confidential Information: shall be limited to information that any producing party, including third parties, in good faith, believes to contain (a) current and past (to the extent they reflect on current) methods, procedures, and processes relating to the pricing of pharmaceuticals; (b) current and past (to the extent they reflect on current) marketing plans and methods; (c) current and past (to the extent they reflect on current) business planning and financial information; (d) trade secrets; (e) past and current company personnel or employee information; and (f) other “CONFIDENTIAL” information (as defined in Paragraph 3) the disclosure of which is likely to cause competitive or commercial injury to the producing party.

PO ¶¶ 3 & 5². Pursuant to ¶ 17 of the PO the party designating information as confidential or highly confidential, in this case the defendants, bears the burden of demonstrating the propriety of such designations. This is in harmony with the many cases, both in the First Circuit and nationwide, which presume judicial records should be publicly available. As detailed below, defendants are wholly unable to meet their burden to keep their documents hidden from

² Plaintiffs challenged the defendants’ designation of summary judgment materials as confidential in a letter dated April 18, 2006, attached as Exhibit B. Under ¶ 17 of the PO, the parties had 21 days to resolve the dispute raised by plaintiffs. The defendants have agreed to unseal their Joint Motion for Summary Judgment and accompanying Rule 56.1 Statement, but have not agreed to unseal the briefs of the four individual Track 1 defendants’ motions, hence the instant motion.

the public, especially in light of their defense that “everyone knew” the truth about the meaning of AWP’s and actual prices.

II. COURTS IMPOSE A HEAVY BURDEN ON PARTIES SEEKING CONFIDENTIALITY

The public has a presumptive right of access to judicial records. *Nixon v. Warner Communications, Inc.*, 435 U.S. 589, 597 (1978); *Anderson v. Cryovac, Inc.*, 805 F.2d 1, 13 (1st Cir. 1985). *See also FTC v. Standard Fin. Mgmt. Corp.*, 830 F.2d 404, 408 n.4 (1st Cir. 1987)(expressly finding that presumption of access applies to civil as well as criminal proceedings). The right extends to materials on which a court relies in determining litigants’ substantive rights, including materials considered in ruling on dispositive motions such as the summary judgment motions at issue here.³ *See Anderson*, 805 F.2d at 8 (approving district court’s protective order that allowed news media access to materials considered in connection with summary judgment motion). *See also In re Providence Journal Co., Inc.*, 293 F.3d 1, 9 (1st Cir. 2002) (“This presumptive right of access attaches to those materials ‘which properly come before the court in the course of an adjudicatory proceeding and which are relevant to that adjudication,’”quoting *FTC v. Standard Fin. Mgmt.*, 830 F.2d at 412-13).⁴ The right derives

³ Just this week the Ninth Circuit strongly reaffirmed the principle that documents used in dispositive motions should be public, *Kamakana v. City and County of Honolulu*, __F.3d __, 2006 WL 1329926 (C.A.9 (Hawaii)). The Court found that a party seeking to seal documents or depositions used in summary judgment must demonstrate by specific facts a compelling reason to keep the documents under seal. *Id.* at *4.

⁴ The First Circuit has found that the right of public access extends to discovery materials, relying on Rule 5(d), relating to public filing of discovery, and Rule 26(c). In making its ruling, the Court found the right particularly strong where the litigation touches on issues of public health and welfare. *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 789-90 (1st Cir. 1988), *cert. denied*, 488 U.S. 1030 (1989).

from the long-held recognition that public access allows “the citizenry to ‘monitor the functioning of our courts, thereby insuring quality, honesty and respect for our legal system.’”

FTC v. Standard Fin. Mgmt., 830 F.2d at 410 (quoting *Matter of Continental Illinois Securities Litig.*, 732 F.2d 1302, 1308 (7th Cir. 1984)). As articulated by Judge Easterbrook, in explaining his practice when faced with motions to seal:

What happens in the halls of government is presumptively open to public scrutiny. Judges deliberate in private but issue public decisions after public arguments based on public records. The political branches of government claim legitimacy by election, judges by reason. Any step that withdraws an element of the judicial process from public view makes the ensuing decision look more like fiat; this requires vigorous justification.

In re Krynicki, 983 F.2d 74, 75 (7th Cir. 1992). Though not absolute, the presumption is “strong and sturdy.... ‘Only the most compelling reasons can justify non-disclosure of judicial records.’”

FTC v. Standard Fin. Mgmt., 830 F.2d at 410 (quoting *In re Knoxville News-Sentinel Co.*, 723 F.2d 470, 476 (6th Cir. 1983)). See also *Poliquin v. Garden Way, Inc.*, 989 F.2d 527, 533 (1st Cir. 1993) (same).

In assessing whether to unseal the exhibits submitted by defendants in support of summary judgment, this Court must undertake a multi-tiered analysis. Defendants seeking to limit access to discovery materials must make a good cause showing that protection is proper under Rule 26(c) of the Federal Rules of Civil Procedure. If good cause cannot be met, then the inquiry ends and confidentiality need not be maintained. If the showing is made, the Court must then balance the privacy concerns with the competing interests in disclosure. Only if, on balance, protection is still warranted may the documents remain under seal.

Whether to limit access is left to the discretion of the Court. Upon a showing of “good

cause,” the court “may make any order which justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue expense or burden, including . . . that a trade secret or other confidential research, development, or commercial information not be revealed or be revealed only in a designated way.” Fed. R. Civ. P. 26(c)(7). The “good cause requirement means that, ‘[a]s a general proposition, pretrial discovery must take place in the public unless compelling reasons exist for denying the public access to the proceedings.’” *Public Citizen v. Liggett Group, Inc.*, 858 F.2d 775, 789 (1st Cir. 1988), *cert. denied*, 488 U.S. 1030 (1989) (quoting *American Telephone & Telegraph Co. v. Grady*, 594 F.2d 594, 596 (7th Cir. 1978), *cert. denied*, 440 U.S. 971 (1979) (additional citation omitted)). A finding of good cause “must be based on a particular factual demonstration of potential harm, not on conclusory statements.” *Anderson*, 850 F.2d at 7. *See also Pansy v. Borough of Stroudsbury*, 23 F.3d 772, 786 (3d Cir. 1994) (“‘Good cause is established on a showing that disclosure will work a clearly defined and serious injury to the party seeking disclosure’.... ‘Broad allegations of harm, unsubstantiated by specific examples of articulated reasoning, do not support a good cause showing’”) (internal citations omitted).

A. The Burden is on the Defendants

The burden of establishing good cause rests squarely on the party seeking protection. *See Leucadia, Inc. v. Applied Extrusion Technologies, Inc.*, 998 F.2d 157, 166 (3d Cir. 1993). This burden must be carried with respect to each document for which a claim of confidentiality is made. *Foltz v. State Farm Mut. Auto Ins. Co.*, 331 F.3d 1122, 1130 (9th Cir. 2003). *Cf. In re Providence Journal*, 293 F.3d at 15 (district court’s refusal to consider document-by-document redaction found insupportable). Here the burden is on the Defendants.

The creation of an umbrella protective order as a means to facilitate discovery does not change the analysis. When challenge is made to the protection of information, the producing party must still establish that a document is properly held confidential. *See Public Citizen*, 858 F.2d at 790; *Franklin v. Parke-Davis*, 210 F.R.D. 257, 260-61 (D. Mass. 2002) (Saris, J.) (rejecting argument that umbrella protective order satisfied good cause requirement by obviating expense and need for document-by-document review and related argument that defendants would be prejudiced by modification because they had relied on order in making productions). *See also In re "Agent Orange" Prod. Liab. Litig.*, 104 F.R.D. 559, 571-72 (E.D.N.Y. 1985), *aff'd*, 821 F.2d 139 (2d Cir.), *cert. denied*, 484 U.S. 953 (1987) (court rejected "reliance" argument "because a permanent exception to the good cause requirement for cases with voluminous documents would make Rule 26(c) meaningless. Defendants do not need such an exception; they may still make a good cause showing for those documents they claim are confidential"); *In re Bank One Sec. Litig.*, 222 F.R.D. 582, 586 (N.D. Ill. 2004) ("Once a protective order is entered, a party must continue to show good cause for confidentiality when challenged"). *In re Krynicki*, 983 F.2d at 75 ("[i]nformation that is used at trial or otherwise becomes the basis of decision enters the public record"). The defendants' argument that everyone in the market was aware of the true prices being charged for drugs, along with the dated and non-confidential nature of the defense documents at issue make it impossible for the defendants to meet their burden of establishing good cause to keep their documents secret.

II. THE “EVERYBODY KNEW” DEFENSE UNDERCUTS THE DEFENDANTS’ CONFIDENTIAL DESIGNATIONS

The defense is centered around the argument that the federal government, through the Medicare Program, and various private payors were well aware of the actual spread or difference between AWP prices and the true transaction prices paid for drugs. Thus, the defendants argue, since “everybody knew” the AWP was an inflated and unreliable number, no one could have been defrauded by the defendants’ statements of AWP, (“numerous government reports that reflect the government’s understanding that AWP was not equal to or a reliable signal for, providers’ acquisition costs...”). Defs. Joint Memo in Support of Summ. Judg., p. 15. *See also* Defs. Joint Memo in Support of Summ. Judg. p. 17 and 21 and Defendants Rule 56.1 Statement, various paragraphs and exhibits, referenced in note 53, p.21 of the Defs. Joint Memo in Support of Summ. Judg. This argument constitutes the bulk of the defendants’ Joint Motion for Summary Judgment and their main Opposition to the plaintiffs’ Motion for Partial Summary Judgment.⁵ The “everybody knew” argument is also advanced by defense experts Gregory K. Bell and Eric M. Gaier.

But if everybody was aware that actual prices were well below AWP, as defendants strenuously argue, then there is no basis for the defendants to keep secret their documents discussing the AWP, WAC and actual transaction or ASP prices for their products, such as Exhibits C (OBI pricing strategy memo, also Pltfs. J&J SJ Exh.14)⁶ and D (AstraZeneca 1997

⁵ *See also* Defendants’ Reply Memorandum in Further Support of Summary Judgment, p.6-15, arguing “everybody knew” in support of no causation and statute of limitations arguments.

⁶ Exhibits to this motion are also identified to where they are cited in Plaintiffs’ Motion for Partial Summary Judgment.

price and profit letter, also Pltfs. AZ SJ Exh. 30). Indeed, in the defendants' version of the facts, many market participants already knew the AWP to WAC spread and were aware of drug prices well below WAC. Thus the defendants have no valid reason to assert blanket confidentiality over all of their documents relating to pricing, especially documents involving prices from over 8 years ago, see Exhibits C, D and E (OBI 96 acquisition price and profit memo, also Pltf. JJ SJ Reply Exh. 7). Documents containing information that, according to defendants, class members already know do not fall within the PO's definitions of "Confidential" or Highly Confidential."

Given their reliance on the "everybody knew" defense, the defendants cannot meet their burden to demonstrate that their internal marketing and pricing documents are entitled to protection under the PO.

III. EVEN THOUGH THEY DESIGNATE ALMOST EVERYTHING CONFIDENTIAL, NONE OF THE DEFENDANTS' DOCUMENTS CONTAIN PROTECTED INFORMATION.

The Defendants have designated the great majority of their documents as "confidential" or "highly confidential" regardless of the actual nature of such documents. Thus the defendants include in their overly broad designations documents which, by their dating from the early 1990s, cannot possibly be relevant to their current situation; documents given to third parties, including marketing materials; and otherwise irrelevant information. Upon review, none of the defendants' documents actually contains information worthy of protection.⁷

⁷ As here, defendants in *Franklin* had initially classified almost every document as confidential. The Court concluded that this action belied defendants' claimed reliance on a provision of the umbrella protective order that prohibited use of any discovery for any purpose other than prosecution of that case. *Franklin v. Parke-Davis*, 210 F.R.D. 257, 260 (D. Mass. 2002). See also *In re Bank One Securities Litig.*, 222 F.R.D. 582, 588 (N.D. Ill. 2004) (Defendant's wholesale designation as confidential of every document produced under agreed protective order did not justify maintaining seal and did not obviate obligation to demonstrate

Plaintiffs' research has revealed no First Circuit case defining the term "trade secret" or the scope of permissible confidential information for purposes of Rule 26(c).⁸ The *Poliquin* Court, however, in finding that materials introduced into evidence were properly released from coverage of a protective order, wrote tellingly:

We have no doubt that, in rare circumstances, material introduced at trial can be safeguarded against disclosure afterwards.... The subject could be national security, the formula for Coca Cola, or embarrassing details of private life....

One generalization, however is safe: the ordinary showing of good cause which is adequate to protect *discovery material* from disclosure cannot alone justify protecting such material after it has been introduced at trial.

Poliquin, 989 F.2d at 533 (citations omitted; emphasis in original). The Court cited to cases recognizing the presumptive right of access once information has been relied upon for a substantive ruling affecting litigants' rights. *Id.* The Court similarly rejected defendant's attempt to seal a video deposition based on defendant's claim that the witness testified to highly confidential and proprietary information including business plans, customer profiles and internal procedures. The Court concluded that the videotape "contain[ed] nothing remotely comparable to, say, the formula for Coca Cola or even an important trade secret." The Court continued, "Garden Way's business methods are discussed but there are no startling revelations. The disadvantages of disclosure relate to future litigation, not the conduct of Garden Way's business." *Id.* at 533-34. *See also Republic of the Philippines v. Westinghouse Elec. Corp.*, 949

good cause as to each document for which defendant sought impoundment).

⁸ Massachusetts applies the definition of "trade secret" in comment b to the *Restatement (First) of Torts*, § 757 (1939). *See Burten v. Milton Bradley Co.*, 763 F.2d 461, 463 and n.2 (1st Cir. 1985); *Phillip Morris, Inc. v. Reilly*, 113 F. Supp.2d 129, 135-36 (D. Mass. 2000), *aff'd*, 312 F.3d 24 (1st Cir. 2002).

F.2d 653, 660-61 (3d Cir. 1991)(same considerations that underlie right of access to trials apply to documents considered in ruling on dispositive motions, public has right to assess correctness of judge's actions and decision).⁹

A. Many of the Challenged Practices Have Ceased

Pursuant to the PO, information should only be designated as highly confidential if it relates to “current and past” to the extent they reflect on “current” methods, practices or information. Financial information, marketing or business plans or similar strategic documents from the 1990s can no longer be considered as impacting or reflecting the defendants’ current operations and thus are not properly deemed to be confidential or highly confidentially.

This is especially true in the case of companies who affirmatively state that they have

⁹ In *Contratto v. Ethicon, Inc.*, 227 F.R.D. 304 (N.D. Cal. 2005), a drug product liability case, the court rejected confidentiality claims supported by a declaration, where the declaration failed to identify any specific prejudice or harm that would result from public access. Though defendants asserted that the documents constituted confidential materials subject to protection of the stipulated protective order in that case, the court found no factual support for this conclusion: “Nowhere do they identify any specific secret or otherwise show the specific harm that will result from disclosure of each document.” *Id.* at 308-09. The court lifted the confidential designations: (1) of an internal memorandum addressing statistical information from historical data related to the likelihood of adverse events, finding that it did not contain any proprietary formulas or ideas for research; (2) a manufacturing investigation to resolve problems, because it did not contain “plans for research” as argued by defendants but instead generally summarized past research, without revealing proprietary formulas; (3) sales information that was otherwise publicly available; (4) a draft of a letter submitted to the FDA designed to make clinicians aware of potential adverse events, because the intent of the letter was to eventually disseminate it to prescribers; (5) a letter from the FDA addressing the findings from a visit of an FDA investigator that revealed deviations from regulatory requirements, concluding that the letter might be adverse to defendants’ litigation position but did not contain confidential or proprietary or otherwise proprietary information; and (6) a letter from the FDA that found elements of defendants’ promotional materials and website to allegedly misrepresent the safety and effectiveness of the drug, finding designation improper because the document concerned publicly available information. *Id.* at 309-12. In ruling on several of the documents, the court concluded that passage of time, or staleness, also militated against finding information confidential. *Id.*

changed their practices to no longer allow discussion or marketing the spread. Thus AstraZeneca and J&J have labelled as highly confidential documents indicating that they no longer market the spread. *See* AZ email from 2001 attached as Exhibit F hereto (also AZ SJ Exh.30) and testimony from Astrazeneca's Scott Robbins (attached hereto as Exhibit G, parts of the Robbins transcript were cited and exhibited by both Plaintiffs and AstraZeneca, Pltfs. AZ SJ Exh. 34 and Lucy Fowler Declaration Exh. 21) and Centocor's Laura Glassco, who details how she marketed the spread to physicians and then states that such a practice was subsequently prohibited at Centocor (Exhibit H hereto, also Pltfs. J&J SJ Exh.35).

Many courts have rejected confidentiality claims when the information sought to be protected is not current. *See In re "Agent Orange,"* 104 F.R.D. at 575 (collecting cases rejecting or limiting claims of confidentiality based on staleness of commercial information ranging from one year old to decades old); *In re Bank One Sec. Litig.*, 222 F.R.D. at 589 (defendant failed to demonstrate that the information had "current significance worthy of protection"). *Cf. Campbell Soup Co. v. Giles*, 47 F.3d 467, 471 (1st Cir. 1995) (current marketing plan data found no longer confidential because, by time of ruling, "there was minimal room left for competitive maneuvering" by competitors).

Given the Medicare Modernization Act's discontinuance of the use of AWP, and given the defendants' admitted change in marketing practices, none of the defendants' documents related to summary judgment are sufficiently current to merit keeping them confidential.

B. The Defendants' Designations Are Overly Broad

The defendants also abuse the designation process of the PO by including documents which were plainly seen by third parties, including competitors. This would include marketing

documents shown to physicians, as well as correspondence with publishers and governmental entities. For example, *see* 1) letters to Publishers announcing price changes in 1998 from J&J, BMS and AZ, Exhibits I, J and K hereto (also Pltfs. J&J SJ Exh.10, BMS SJ Exh.8 and AZSJ Exh.17); 2) marketing materials to physicians and other customers Exhibits L, M, N and O (also Pltfs. BMS SJ Exh.26, SP SJ Exh.16, AZ SJ Exh.44 and J&J SJ Exh.25); and 3) communications with the government, including Centocor's J-code application to an agency of the federal government, Exhibit P hereto (also J&J SJ Reply Exh.2) and Warrick's letter to the Nevada Attorney General, Exhibit Q hereto (also SP SJ Exh.1) . It is hard to conceive of how documents plainly sent to third parties can be properly deemed "confidential" or "highly confidential" under the PO.

III. THE PUBLIC HAS A STRONG INTEREST IN DISCLOSURE

Even if the defendants could demonstrate good cause for maintaining impoundment for any particular document, that does not end the inquiry. Rather, the Court must then evaluate whether the interest in secrecy outweighs the public interest in disclosure. The party seeking protection bears the burden of making this showing. *See Leucadia*, 998 F.2d at 166. Even trade secrets do not get automatic protection when balanced against public interest. *Id.* (advisory committee's notes to 1970 amendments to Rule 26(c) "explain that 'courts have not given trade secrets automatic and complete immunity against disclosure, but have in each case weighed their claim of privacy against the need for disclosure'"). Circumstances weighing against confidentiality include information and issues important to the public. *See, e.g., FTC v. Standard Fin. Mgmt.*, 830 F.2d at 412 (case involving a government agency and alleged deceptive trade practices causing consumer losses "patently" presented "matters of significant public concern"

elevating the threshold showing for impoundment”); *Republic of the Philippines v. Westinghouse*, 949 F.2d at 664 (finding legitimate public interest outweighing confidentiality claim and recognizing that civil matters that reflect alleged fraud are of legitimate public interest); *In re “Agent Orange,”* 104 F.R.D. at 572 (gain in public understanding about the nature of the issues in the litigation and contamination from dioxin warranted disclosure of summary judgment documents).

This case raises claims of consumer fraud on a massive scale that has inflated the cost of prescription drugs for state governments, insurers, employers, and millions of citizens. The compelling public interest in contemporaneous review of the basis for this Court’s decisions on the pending summary judgment motions warrants disclosure of defendants’ documents. The public certainly has a strong interest in learning whether it has been overcharged for hundreds of prescriptions, and the exact nature of such overcharges.

Moreover, as discussed above, it is difficult to conceive of how the defendants can claim the public has no interest in learning about how it was charged for and marketed various medicines, when the defendants claim that the public already knew of the defendants’ schemes.

V. CONCLUSION

For the reasons stated above, all the defense documents used in support and opposition to the pending summary judgment motions should be unsealed by this Court. The defendants are unable to sustain their heavy burden of proving such documents actually are confidential or highly confidential, especially given the nature of their defense, namely that “everyone knew” AWP pricing was fraudulent, and given the defendants’ abuse and overly broad assertion of confidential designations.

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Respectfully submitted,

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Certification Under Local Rule 37.1

Pursuant to Fed.R.Civ.P. 37(a)(2) and Local Rule 37.1, undersigned counsel certifies that Plaintiffs have conferred with counsel for defendants regarding the issues raised in this motion, but the parties were unable to resolve the dispute.

/s/ John Macoretta

CERTIFICATE OF SERVICE

I hereby certify that I, John A. Macoretta, an attorney, caused a true and correct copy of the foregoing **PLAINTIFFS' MOTION TO UNSEAL ALL CONFIDENTIAL OR HIGHLY CONFIDENTIAL DESIGNATED DOCUMENTS USED IN SUMMARY JUDGMENT PROCEEDINGS** to be delivered to all counsel of record by electronic service by sending on May 19, 2006, a copy to LexisNexis File & Serve for posting and notification to all parties.

By /s/ John A. Macoretta